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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,528	10/13/2000	David M. Stern	0575/62096/JPW/JML	8939

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12/19/2002

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EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/687,528

Applicant(s)
Stern et al.

Examiner
Shin-Lin Chen

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6, 9, and 11-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6, 9, and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1633

DETAILED ACTION

Applicants' amendment filed 10-15-02 has been entered. Claims 4, 5, 9, 11, 13 and 14 have been amended. Claims 1, 2, 7, 8, 10 and 15-24 have been canceled. Claims 3-6, 9 and 11-14 are pending and under consideration.

As discussed in the preceding Official action mailed 4-10-02 (Paper No. 8), this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Appropriate response to "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures" is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 10-15-02 necessitates this new ground of rejection.

Art Unit: 1633

Claim 6 depends on canceled claim 1 or 2 and renders the claim indefinite. It is unclear what is intended to be claimed in claim 6.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-6 and 11-14 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 4-10-02 (Paper No. 8). Applicant's arguments filed 10-15-02 have been fully considered but they are not persuasive.

Applicants amended claim 9 to read on the V-domain of soluble receptor for advanced glycation endproduct (sRAGE) and argue that the rejection has been obviated (amendment, p. 11). This is not found persuasive because of the reasons of record. The scope of the inhibitor of RAGE in claims 3-6 and 11-14 remain unchanged and, therefore, claims 3-6 and 11-14 remain rejected under 35 U.S.C. 112 first paragraph written description rejection for the reasons of record.

Art Unit: 1633

5. Claims 3-6, 9 and 11-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reduction of smooth muscle proliferation and migration in carotid artery by treating Fatty Zucker rat with soluble RAGE (sRAGE) via intraperitoneal injection, does not reasonably provide enablement for any method for preventing exaggerated restenosis in a diabetic subject by administering to said subject any polypeptide inhibitor of RAGE *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 4-10-02 (Paper No. 8). Applicant's arguments filed 10-15-02 have been fully considered but they are not persuasive.

Applicants amended claim 9 to read on the V-domain of soluble receptor for advanced glycation endproduct (sRAGE) and amended claims 4, 5, 9, 11, 13 and 14 to read on preventing exaggerated restenosis in a diabetic subject by using inhibitor of RAGE, and argue that the rejection has been obviated (amendment, p. 2, 3, 11). This is not found persuasive because of the reasons of record. The scope of the inhibitor of RAGE in claims 3-6 and 11-14 remain unchanged and, further, the specification only discloses reduction of smooth muscle proliferation and migration in carotid artery by treating Fatty Zucker rat with soluble RAGE (sRAGE). The specification fails to provide adequate guidance and evidence that any inhibitor of RAGE, including sRAGE or V-domain of sRAGE, can **prevent** exaggerated restenosis in a diabetic

Art Unit: 1633

subject. Therefore, claims 3-6, 9 and 11-14 remain rejected under 35 U.S.C. 112 first paragraph enablement rejection for the reasons of record.

6. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 10-15-02 necessitates this new ground of rejection.

The phrase "V-domain of soluble receptor for advanced glycation endproduct (sRAGE)" in claim 9 is considered new matter. The amendment filed 10-15-02 indicates that page 19, lines 27-30 and page 18, SEQ ID No. 5 provide support for the amended claim 9. However, none of those pages mention "V-domain" of sRAGE and the specification fails to provide sufficient disclosure for "V-domain" of sRAGE. Thus, the phrase "V-domain of soluble receptor for advanced glycation endproduct (sRAGE)" in claim 9 is considered new matter.

Conclusion

No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1633

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

